REMARKS

The Office Action of September 26, 2008 has been carefully considered.

Claims 43-62 have now been canceled, and replaced by a new set of claim 63-82, written in proper form for US practice. The rejection of claims under 35 USC 112, 2nd paragraph, is thought to have been rendered moot by this new set of claims.

In addition, the rejection of claims 43 and 49 under 35 USC 112, 1st paragraph, is thought to have been rendered moot by this new set of claims.

The rejection of claim 47 under 35 USC 112, 1st paragraph, may still be applicable, since new claim 65 recites that the agent may be selected from a group of pharmaceutical agents of various types, which are disclosed but not exemplified in the specification.

Contrary to the statement made in the Office Action, the recitation of claim 65 provides no under experimental burden. The basis for the invention, increasing the initial hollow volume of particles, is set forth in claim 63; claim 65 provides only the step of contacting the particles with an additional agent which is capable of changing a property of the particles. This agent can be a pharmaceutical; as noted in the Office Action certain anti-allergic agents are exemplified in the specification. However, the other agents claimed are well known in the art, and no reason has been given, other than the large number of agents possible, why one of ordinary skill would have any difficulty practicing the invention, since it is the step of "contacting" which is important.

It is noted that the invention is NOT directed to treatment of disease, which implies unpredictability, but only to preparation of particles which may contain a pharmaceutical agent.

Withdrawal of this rejection is requested.

Claims 43-52, 55-60 and 62 have been rejected under 35 USC 102(b) over Trofast et al, while claims 43-62 have been rejected under 35 USC 103(a) over Trofast et al in view of Gurfein et al.

The invention is now directed to a method for producing drug delivery particles with improved drug delivery characteristics by altering aerodynamic properties thereof. In this method, pharmaceutically acceptable hollow particles are obtained, which comprise a water soluble material, the particles are contacted with a pharmaceutically acceptable fluid that increases the initial hollow volume of the particles, wherein said fluid comprises at least 94% by volume of a non-solvent for the particles, to obtain particles having increased initial hollow volume, and the drug delivery particles are harvested. Support for this new claim can be found in Example 10 of the specification, and in claim 43, now canceled.

Trofast et al discloses a process for providing water soluble micronized substances that can be produced, stored and used while maintaining the aerodynamic (and other) properties required for inhalation of such substances. This process is carried out by reducing residual water from the micronized substance by drying, conditioning the dried micronized substances with a solvent, and then eliminating residual solvent by storing in a dry place, for example a vacuum. The specific particle properties that Trofast et al seeks to maintain are particle size, particle form, hygroscopicity and aerodynamic diameter; see page 3, line 35. Trofast et al notes the particle size of the micronized particles is identical before and after treatment.

While the invention is directed to a method of treating hollow particles to increase the initial hollow volume of the

particles, Trofast et al is directed to treatment of micronzied particles, which are *neither spherical nor hollow*. Since Trofast et al *does not treat hollow particles*, this reference cannot anticipate the invention.

Further, the invention is directed to changing the aerodynamic properties of the original particles. Trofast et al actually teaches away from the invention, because Trofast et al seeks to ensure maintenance of the aerodynamic properties.

Gurfein et al teaches preparing a solution or suspension of particles, forming graded drops, freezing the drops, and lyophilizing the frozen drops to remove solvent by sublimation, to obtain thereby microporous anhydrous granules.

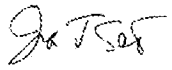
According to the invention, the hollow particles are contacted with a non-solvent to increase their hollow volume, and it is submitted that there is a clear distinction between the two processes.

Further, Gurfein et al does not modify any particle features by dispersing (contacting) granules in a non-solvent, and only disperses the granules in fluids which are capable of lyophilization. Gurfein et al teaches the use of a polymer to adjust the viscosity of the medium and hence the size of the droplets. The presence of the polymer will not effect the lyophilization process to produce microporous particles.

As neither of the cited references teaches or suggests a process for increasing the hollow volume of hollow particles, withdrawal of these rejections is requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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